Remarks/Arguments

Prior to the present amendments, claims 29, 30, 32-36, 40-48 and 56 were pending in this application, and were rejected on various grounds. Claims 29 and 42 have been amended, and claims 33-36 and 56 have been canceled. The amendment of claim 42 is of formal nature and serves to correct a typographical error pointed out by the Examiner. The amendment of claim 29 is supported at least by Examples 1 and 2, and does not add new matter.

Claim Objections

Claim 36 has been objected to "as being of improper dependent form for failing to further limit the subject matter of a previous claim." The cancellation of claim 36 moots this rejection.

Claim 42 was objected to due to its recitation of "a" before "carvedilol." The foregoing amendment of claim 42 is believed to obviate this rejection.

Claim Rejections - 35 USC 112, first paragraph - scope of enablement

Claims 29, 30, 31-36, 40-48 and 56 were rejected as allegedly not being supported by an enabling disclosure in the specification. The Examiner acknowledged sufficient enablement for "a method of inhibiting fluprostenol-induced cardiac hypertrophy in rats."

Without acquiescing in the rejection, or the Examiner's arguments advanced in support of the rejection, claims 31, 33-36, and 56 have been canceled. The rejection of the remaining claims is respectfully traversed.

The efficacy of IFN-γ in the treatment of cardiac hypertrophy has been tested in well recognized *in vitro* assays and *in vivo* animal models (see Examples 1 and 2). As discussed at page 4, lines 20-23, page 12, line 1 - page 13, line 6, Examples 1 and 2, and the references cited therein, the role of $PGF_{2\alpha}$ and its derivatives in the pathogenesis of cardiac hypertrophy was well known in the art at the priority date of this application, as

was the relevance of results obtained in $PGF_{2\alpha}$-stimulated cardiac hypertrophy assays for identifying agents for the treatment of $PGF_{2\alpha}$-associated cardiac hypertrophy. Accordingly, the present application, including the results disclosed in the Examples, clearly provides sufficient enablement not only for methods of inhibiting fluprostenol-induced cardiac hypertrophy in rats, as the Examiner has suggested, but for methods directed to the treatment of $PGF_{2\alpha}$-associated cardiac hypertrophy (now recited in claim 29) in general.

It is well established that the scope of enablement must only bear a "reasonable correlation" to the scope of the claims, see, e.g. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). It is also well established that if the art is such that a particular model is recognized as correlating to a specific condition, then reasonable correlation will be accepted, unless the Examiner provides evidence that such correlation does not exist. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications). A rigorous or an invariable exact correlation is not a requirement. *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed Cir. 1985).

As discussed above, in the present case, Applicants provided by *in vitro* and *in vivo* data for the claimed use of IFN-γ, using art recognized assays. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

Claims Rejections - 35 USC 112, first paragraph - written description

Claim 56 was rejected for alleged lack of adequate written description. Without acquiescing to this rejection, claim 56 has been cancelled, therefore, its rejection is moot.

Claim Rejections - 35 USC 112, second paragraph

Claims 29, 30, 31-36, 40-48 and 56 were rejected under 35 USC 112, second paragraph as "indefinite" for allegedly being unclear in stating whether the patient treatment has already suffered from hypertrophy, or was at risk of hypertrophy.

Claims 31, 33-36, and 56 have been canceled. Claim 29 now clearly recites that the patient is diagnosed with cardiac hypertrophy prior to treatment. Accordingly, the Examiner is requested to withdraw the present rejection.

All claims are believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39766-0068A2D1). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: November 19, 2004

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